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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 08/817,704
Filing Date: August 25, 1997
Appellant(s): SWAAK, ANTHONIUS J.

Krista Weber Powell
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/07/06 appealing from the Office action mailed 12/16/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims

involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters. The brief is deficient because the rejections of record are under the first paragraph of 35 U.S.C. § 112 for inadequate written description, particularly, the introduction of new matter into the claims. Accordingly, by definition, it is the Examiner's position that the specification does *not* disclose the claimed invention thus, Appellant's summary *must* be deficient if it attempts to cite support for the invention in the specification. The specifics of the deficiencies are set forth below.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 18, 20, 23-26, 31, and 34-36 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a method of treating consisting of identifying a patient (now an RA patient), administering Epo to said patient, and identifying that said patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints has a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints after treatment.

B) a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level consisting of identifying a patient (now an RA patient), administering Epo to said patient, and identifying that said patient has an ameliorated erythrocyte sedimentation rate or C-reactive protein level.

A review of the specification discloses that the new limitations are found only in a specific example in the context of treating ACD patients (i.e., a specific subset of RA patients) with a specific dosage of Epo, for a specific timeframe, and not in the broad context of the instant claims.

(10) Response to Argument

Part A) Appellant argues that, "While, it was thought that ACD rheumatoid arthritis patients are a distinct from [*sic*] rheumatoid arthritis ("RA") patients as a whole, no support has been cited for this contention".

The specification discloses at page 2 that "nearly 50%" of RA patients also develop ACD, thus, the Examiner's position that ACD patients are a subset of RA patients.

Appellant argues "It was thought that because the examples included ten (10) ACD RA patients, Appellant's method should be limited to ACD RA patients".

A more accurate characterization of the instant specification would be that the brief specification comprises a single example in which the results of administering a single type, and dosage, of Epo, over a single time course, to 10 patients pre-selected for ACD, are disclosed.

Appellant cites original Claim 5 in support.

Original Claim 5, "Use of Epo or a substance having Epo-like activity in the preparation of a pharmaceutical for the

treatment of symptoms associated with RA", bears little resemblance to the method of the instant claims.

Appellant cites the Abstract in support.

The Abstract comprises just two sentences relevant to the claimed method, "A particularly beneficial result is seen in patients suffering from rheumatoid arthritis (RA). Significant effects are seen in clinical variables such as morning stiffness, swollen joints, and the like". It is clear that the Abstract does not disclose all of the limitations of the claimed invention, e.g., loss of grip strength, painful joints, identifying erythrocyte sedimentation rate or C-reactive protein levels, etc.

Appellant cites page 3, lines 3-17 of the specification.

Said cite does not teach the claimed method.

Appellant cites original Claims 8 and 9 and page 3, lines 21-30 of the specification in support of the assertion that the specification supports the use of any type of Epo in the claimed method.

Original Claim 8 recites only human Epo and original Claim 9 recites only recombinant Epo. The cite at page 3 of the specification discloses generic Epo *only* in the context of treating chronic inflammations.

Appellant again cites the original "Use" claims in support.

A review of the original claims reveals that they fail to recite, even in a "Use" context, many of the limitations of the instant claims. For example, the original claims do not disclose identifying a patient with reduced morning stiffness, loss of grip strength, painful joints, or swollen joints after treatment with Epo. Likewise, the original claims do not recite either identifying nor ameliorating erythrocyte sedimentation rate nor C-reactive protein levels. Neither do the original claims recite the time courses of Claims 31-36.

Appellant argues that "Evidence and actual examples of methods of treatment are shown starting on page 6 of the as-filed specification. The various acts of the method claims are supported by this section".

Asset forth above, the specification is more accurately characterized as showing a single example in which the results of administering a single type, and dosage, of Epo, over a single time course, to 10 patients pre-selected for ACD.

Appellant cites original Claims 5 and 6 in support.

As with the other original claims, original Claims 5 (set forth above) and 6 fail to recite the method of the instant claims. Appellant is merely picking bits and pieces, or fragments, of the claimed invention out of the specification and original claims. Nowhere does the specification nor original

claims disclose or recite the currently claimed method in the context of a generic RA patient.

Part B) In the arguments of pages 14, 15, and the first half of 16, Appellant reiterates the arguments of Part A). Appellant cites page 7 lines 19-31 and page 17 in support of the method of ameliorating erythrocyte sedimentation rate or C-reactive protein levels in a generic RA patient.

A review of the cites reveals that the cite at page 7 discloses only that a decrease in erythrocyte sedimentation rate and C-reactive protein levels was found in the 10 experimental ACD patients. Thus, the cite does not provide sufficient support for the claimed method. Page 17 comprises the original claims which do not recite anything regarding erythrocyte sedimentation rate or C-reactive protein levels.

In total then, it remains the Examiner's position that the specification and claims as filed cannot support the methods of the instant claims. The specification does not disclose that the Experimental section as merely exemplary nor even a preferred (but not limiting) embodiment. The specification discloses that,

"This study focused on the effects of r-hu-Epo on RA disease activity parameters. It is a part of a project studying the pathogenesis of ACD and possible therapeutic strategies. The effect of r-hu-Epo on the anaemia and iron metabolism is reported in more detail (21).

Ten patients with RA (22) were studied, fulfilling the criteria for ACD as proposed by Cartwright (8). ACD was

confirmed by measuring stainable iron in a bone marrow preparation…".

The specification goes on to describe the selection criteria of a specific subset of ACD patients for treatment. Clearly then this method of the specification applies only to a limited ACD subset of RA patients, and then only with recombinant human Epo. Appellant's argument would seem to be that it would be obvious to apply the method to all RA patients (as is claimed). It is well-established, however, that obviousness is not the standard for a finding of adequate written description.

Contrary to appellant's assertions and implications, the specification makes clear that patients were *not* selected/identified due to suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints. Indeed, the specification specifically discloses that the patients were selected/identified employing ACD criteria as set forth above. Again, while certain method steps might be obvious, obviousness is not the standard for a finding of adequate written description. Accordingly, the rejections of record are proper and should be affirmed.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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10/24/06

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